**Innovations for Poverty Action Institutional Review Board (IRB)**

**ORIGINAL APPLICATION**

**The cover page and study protocol template included in this application provide researchers with an opportunity to describe their study and, in particular, efforts to effectively manage any risks or effects toward human subjects. IPA IRB will review the study using the cover page and study protocol as well as all required and supplementary documents to determine if the design effectively safeguards participants.**

**Required Documents:**

[ ]  Completed cover page [first two pages of this application form]

[ ]  Completed study protocol [the rest of the application form]

[ ]  Survey(s) in **English[[1]](#footnote-1)**

[ ]  Informed consent(s) in **English[[2]](#footnote-2)**

[ ]  CITI or equivalent human subjects certifications for all research staff, if not already on file

**Supplementary Documents[[3]](#footnote-3):**

[ ]  **MOU** or letter of support from partner organization(s)

[ ]  **Data use sharing agreement** with relevant partner or sponsoring organization(s)

[ ]  Marketing materials to recruit subjects, *if IPA is involved in designing or implementing*

*recruitment*

[ ]  IRB approval from other institution(s), including any local IRB(s)

[ ]  Exemption form, if applying for exempti**o**n from IRB review

[ ]  Proof of PI approval via email, if this form is not signed or submitted by PI

[ ]  Any other relevant documentation

**When complete, please file this application form, including all its attachments, via** [**https://www.poverty-action.org/researchers/working-with-ipa/irb**](https://www.poverty-action.org/researchers/working-with-ipa/irb)**.**

Do **not** file this application via humansubjects@poverty-action.org unless you cannot submit it through the website due to a technical error.

The only exception refers to the certification of human subjects training. If not already on file, please email these certificates to humansubjects@poverty-action.org. Please do not hesitate to reach out to humansubjects@poverty-action.org with any additional questions you may have. In your email’s subject, please mention your study’s name, your country, and your study protocol’s number (from your approval letter, if already available).

**COVER PAGE**

**Date of Application:** Click here to enter a date.

**Title of Study:** Click here to enter text.

**Former or alternate titles if known:** Click here to enter text.

**Project Contact for IRB:** Click here to enter text.

**Countries & Locations:** Click here to enter text.

**Anticipated Start Date & End Date (be specific about date you plan to begin fielding study):**

**Start:** Click here to enter a date.

**End:** Click here to enter a date.

## Exemption

**Will you apply for an exemption from continuous IRB review?**

[ ]  **Yes**

[ ]  **No**

**If “Yes”, please complement this application with an additional, separate application for exemption. The corresponding form can be found at and submitted through** [**poverty-action.org/irb**](https://www.poverty-action.org/irb)**.**

## Certifications

**I certify that the statements herein are accurate and complete. I agree to inform the Board should there be any changes in the protocol or problems arising from this protocol. I accept responsibility for the conduct of this research, the supervision of research personnel and human subjects, and the maintenance of informed consent documentation as required.**

**Do you or any family members (spouse, child, or domestic partner) have any incentives or interests, financial or otherwise, that may affect or be affected by the conduct of this research or that may affect the protection of the human subjects involved in this project?**

[ ]  Yes [ ]  No

**If yes, please attach a description of the interest.**

Click here to enter text.

**Primary Investigator's name, typed**

Click here to enter text.

**Primary Investigator's signature**

**(or attach an email stating PI’s acknowledgement of this application)**

**Date** Click here to enter a date. **Signature**

**STUDY PROTOCOL**

**Note that points I. through VIII. (below) are called your “study protocol”, which will be referred to in later IRB submission forms, including renewals and amendments.**

# I. Project Team and Study Collaborators with Access to PII

IPA IRB must have records of current human subjects certifications on file for **ALL Principal Investigators** as well as any other research staff with access to PII. These last for only **three years** before a refresher course must be taken.

**Principal Investigator(s):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Email | Will **not** see PII | Gets other IRB approval | Date of most recent Human Subjects Certification? |
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**If any of the above PIs will be getting IRB approval at their institutions, please submit copies of these documents.**

**Name, Address, Phone Number, e-mail address of Primary Investigator:**

Click here to enter text.

**All other research personnel** **and / or any personnel with access to more than 10% of your sample’s PII. Research personnel include but are not limited to: research associates, research managers, data coordinators, country directors, and deputy country directors. Note if personnel will not see PII:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name | Email | Role | Will **not** see PII | **OR** | Date of most recent Human Subjects Certification? |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | [ ]  | **OR** | MM/DD/YYYY |
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**Will anyone else have access to your study’s PII (this may include implementing partners)?**

|  |  |  |  |
| --- | --- | --- | --- |
|  Name | Email | Role  | Date of most recent human subjects certification? |
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## Funding

**Name of sponsoring agencies and contact names, if known.**

Click here to enter text.

**Will this project receive ANY federal funding[[4]](#footnote-4)?**

[ ]  **Yes**

[ ]  **No**

**Will this project receive ANY funding from MIT/JPAL?**

[ ]  **Yes**

[ ]  **No**

## Partner Organization(s)

List any partner organizations and contact names.

Click here to enter text.

Do you have a data sharing agreement with any of your partner organizations?

[ ]  Yes

[ ]  No

*If you have a data sharing agreement, please include it with your application materials.*

# II. Purpose/Background/Significance.

**Briefly describe the purpose of the proposed study, including a brief background or context to the evaluation and an explanation of why the study is valuable and significant.**

Click here to enter text.

# III. Test Procedures and Measures.

1. **Describe the study design.**

Click here to enter text.

1. **Specify treatments and control groups.**

Click here to enter text.

1. **If IPA is responsible for marketing, specify any marketing used and describe your recruitment tactics (if you are using marketing, you must attach copies of the marketing materials along with the rest of your application). You may leave this blank if IPA is not responsible for designing or implementing recruitment materials.**

Click here to enter text.

1. **Specify the timing of any surveys that will be administered. Clarify whether the surveys will be translated into local languages, and who will be responsible for translations. You do not need to provide copies of surveys in local languages; we only need to hear your translation procedures.**

Click here to enter text.

1. **If applicable, describe how the treatment will be delivered.**

Click here to enter text.

1. **Provide an explanation of ALL measures to be collected and sources for ALL data to be obtained. This includes both intermediary and outcome measurements.**

Click here to enter text.

1. **Provide any other information relevant to test procedures and methods.**

# IV. Subject Population

**Describe who study participants are, how many will be involved, and how you will gain access to the population.**

Click here to enter text.

**Will the study seek out any of these vulnerable populations?**

[ ]  **Children**

[ ]  **Pregnant Women**

[ ]  **Prisoners**

[ ]  **Veterans**

[ ]  **Others (please describe below)** *Vulnerable populations are any group whose ability to provide a free, voluntary, and informed consent is constrained.*

**Elaborate below if applicable, and describe any special procedures used to safeguard these subjects.**Click here to enter text.

**Will the study ask about any of the following sensitive topics? This does not mean the study is high risk, however, a topic that is innocuous in one context may be sensitive in another.**

[ ]  **Governance issues**

[ ]  **Sexual Health or Behaviors**

[ ]  **Physical Abuse**

[ ]  **Involvement in Illegal Activities**

[ ]  **Suicidal Ideation**

[ ]  **Others (please describe below)**

**Elaborate below if applicable.**

Click here to enter text.

**Will study participants be compensated for their time?**

[ ]  **Yes, participants will be compensated**

[ ]  **No, participants will not be compensated**

**If so, what value and form will the compensation take? How was this decided?**

Click here to enter text.

# V. Informed Consent

## How will the informed consent be obtained?

**Please specify whether the consent will be written, verbal, or of any other type.**

[ ]  Written

[ ]  Verbal

[ ]  Requesting Waiver (Partial or Full)

**If “verbal”, explain why you seek permission for verbal consent, e.g. why written consent will not be practically feasible.**

Click here to enter text.

**If you are requesting a waiver of consent, please note OHRP’s standards (sections c and d of** [45 CFR 46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116)**) for waivers. Explain below (a) whether the project poses minimal risk to subjects, (b) whether the waiver will adversely affect the rights and welfare of subjects, (c) whether the research could be practicably carried out without a waiver, and (d) how the study team plans to follow up to provide subjects with additional pertinent information, as appropriate.**

Click here to enter text.

**Will you record any audio?**

[ ]  Yes

[ ]  No

**If yes, please describe procedures for storing and destroying audio files. Note that you must inform participants about audio recording procedures unless you can argue for why this element of the informed consent should be waived for your study.**

Click here to enter text.

**Will you collect any GPS data?**

[ ]  Yes

[ ]  No

**If yes, please describe why you are collecting GPS data and whether this poses additional risks to subjects.**

Click here to enter text.

**Who will pay for the surveyors, IPA or the Partner Organization?**

[ ]  IPA

[ ]  Partner Organization

[ ]  Other. Specify: Click here to enter text.

# VI. Data Collection Procedures

**How will the data be collected? Check all that apply.**

[ ]  Electronically

[ ]  Paper

[ ]  Third party administrative data

[ ]  Recordings

[ ]  Other

**Add any details you deem instructive.**

Click here to enter text.

# VII. Possible risks of the study, including for participants and IPA or partner organization staff

**Discuss possible risks and benefits to study participants. This includes financial, physical or emotional risk. Regarding a risky study location and potential risks to staff, please elaborate. Please describe plans to manage or mitigate all risks.**

Click here to enter text.

# VIII. Treatment of Data

**Describe all data security procedures the project will take to maintain confidentiality of human subjects, including: 1) paper data security procedures (collection, transfer and storage), 2) data security procedures for digital data collection data security procedures, 3) monitoring of data security procedures to ensure adherence.**

**APPENDIX:**

**Innovations for Poverty Action Institutional Review Board (IRB)**

**CONSENT FORM CHECKLIST AND TEMPLATE**

The following provides you with a checklist of items that will be assessed when examining your consent procedures. Below, you will also find a consent template. You can also reference OHRP’s consent form requirements [here](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116).

Please note: If you believe including any of the below will bias the study, tell the Human Subjects Committee why in the body of your email.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **n/a** |
| Consent is submitted to IPA IRB in **English** (and administered in the respondent’s language, with both translations and back translations performed to ensure accuracy) | ☐ | ☐ | ☐ |
| Surveyor introduces him/herself and **explains** his/her affiliation | ☐ | ☐ | ☐ |
| Statement that the study is **research** rather than routine care or programming (and explaining the difference as needed) | ☐ | ☐ | ☐ |
| Describes the purpose of the research | ☐ | ☐ | ☐ |
| Description of all procedures to be followed, and identification of any procedures which are experimental. ***If applicable***, this includes a statement alerting participants about the random nature of the experiment. | ☐ | ☐ | ☐ |
| Exculpatory and coercive language are excluded | ☐ | ☐ | ☐ |
| Jargon and confusing language are excluded. Ensure phrasing is clear, comprehensible and concise. | ☐ | ☐ | ☐ |
| Potential participant is “**invited**” not “chosen” to participate | ☐ | ☐ | ☐ |
| The individual and global benefits of the study are both adequately described, as well as the contents of the survey (i.e. demographics, education, savings behaviors, etc.) | ☐ | ☐ | ☐ |
| Risks and discomforts are adequately described (i.e. Might some of your questions make respondents feel uncomfortable?) | ☐ | ☐ | ☐ |
| Statement that participation is voluntary | ☐ | ☐ | ☐ |
| Statement that participants do not have to answer all questions and that there is no penalty for skipping any question | ☐ | ☐ | ☐ |
| The duration of overall study: Will there be a follow-up survey? When? How many follow-up surveys? ***If applicable:*** include space to ask whether they agree to be contacted by the researchers in the future, and the purpose of such future contact (i.e. new study, follow-up, etc.)**Note:** Researchers should not re-contact participants once the study is closed unless they have given their permission for them to do so for that purpose | ☐ | ☐ | ☐ |
| The time it will take to complete survey is noted | ☐ | ☐ | ☐ |
| Procedures for any audio or visual recording including:1. That recordings will be taken and what type (audio or video)
2. When the recordings will be taken if known; the consent can say “at a random time in the interview” if unknown
3. Why the recordings will be taken
4. What the recordings will be used for
5. How the recordings will be kept confidential
6. If and when the recordings will be destroyed
7. Whether being recorded in this manner is a requirement of participation, and if not, then how participants can express that they would not like to participate
 | ☐ | ☐ | ☐ |
| Notification of whether you intend to take GPS coordinates, why you are collecting GPS coordinates, whether this poses any risks to participants, and whether this is a requirement of participation | ☐ | ☐ | ☐ |
| Explanation that **identifiable** data will not be shared outside of predetermined, authorized parties. | ☐ | ☐ | ☐ |
| Sweeping statements that broadly **guarantee** absolute confidentiality are excluded. Avoid statements using “absolute/utmost confidentiality”, “strictly confidential”, and “your responses will be kept a secret” | ☐ | ☐ | ☐ |
| A statement about whether participants' information might be stripped of identifiers and used for future research | ☐ | ☐ | ☐ |
| ***For studies dealing with potentially criminal activities*** *–* Include a confidentiality disclaimer: “Researchers will keep your information confidential to the extent possible and allowable by law.” From a human subjects perspective, it is less risky to collect this information in a manner that would not identify the respondent, e.g. list randomization. Studies should also be aware of the country’s **reporting requirements,** such that people are obligated to disclose certain kinds of information about illegal activities (including allegations of abuse or neglect, which sometimes must be reported to the police by law.) | ☐ | ☐ | ☐ |
| Local, **accessible** contact for questions about the research study. ***Must include a phone number*** and must be someone who speaks their language or with easy and immediate access to a translator | ☐ | ☐ | ☐ |
| Contact for subjects that have questions about their rights as research participants (***not*** research team; must be an IRB or REC), and information about whom to contact in the event of a research-related injury | ☐ | ☐ | ☐ |
| Statement that refusal to participate or withdrawal at any time will not lead to penalty or loss of benefits | ☐ | ☐ | ☐ |
| ***If applicable****:* A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit | ☐ | ☐ | ☐ |
| ***If applicable:*** Any compensation for participation, such as a payment or gift. Be specific (This may be waived if there is reason to believe it would bias the study results, but inclusion/exclusion must be addressed in your submission materials.) | ☐ | ☐ | ☐ |
| Clearly state if there are any costs associated with study participation, and if so, specify what they are. If there are no costs, (which is usual for social-behavioral studies) this section may be omitted.  | ☐ | ☐ | ☐ |
| Space to record response to consent (yes/no) and ***if applicable***: space to record response to consent to audio/visual recording and GPS coordinates (if being collected). | ☐ | ☐ | ☐ |
| Check with the local Data Protection Officer in your country office to obtain the necessary information that needs to be included in the consent form per country data protection regulation requirements. | ☐ | ☐ | ☐ |
| Sufficient opportunity to ask questions | ☐ | ☐ | ☐ |
| ***For written consent only:*** Space for signature and/or thumbprint | ☐ | ☐ | ☐ |
| Circumstances where participation could be terminated by PI | ☐ | ☐ | ☐ |
| Consequences of withdrawal and any requirements for orderly withdrawali.e. For a Focus Group Discussion, “If decide you would like to leave the discussion at any time, please exit the room quickly and quietly to minimize disruption to the other participants. If you would like your discussion statements to be removed from any research materials, you should contact xx at sampleemail@organization.org within one week.” | ☐ | ☐ | ☐ |
| ***If applicable****:* description of any alternative procedures or treatment that may be available and advantageous to the subject  | ☐ | ☐ | ☐ |
| ***If applicable****:* a statement that the particular treatment or procedures may involve risks to the subjects that are currently unforeseeable | ☐ | ☐ | ☐ |

***Sample Consent Form Template***

*The following is intended only as a sample; it should be modified to fit the specific study. If there are components in the template that do not apply to your study (i.e. information on follow-up surveys) then feel free to omit them*

**\_\_\_\_\_Respondent Code**

***Informed Consent****Study Title*

Hello, my name is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. (Enumerator name)

I am a researcher for Innovations for Poverty Action, a research and policy non-profit that discovers and promotes effective solutions to global poverty problems. We are **inviting** you to participate in this study. This study involves research, which is different from routine care or programming, because we are trying to learn about certain things rather than only providing services.

I am visiting you today because we are a conducting a study about \_\_\_\_\_\_\_\_\_.

1. **Purpose:**

The purpose of this survey is to *\_\_\_\_\_\_\_\_\_\_\_\_*. We hope that this research will help us better understand \_\_\_\_\_\_\_ in order to improve future \_\_\_\_\_\_\_\_\_\_\_\_ (If there is a benefit to participants, state it clearly. Describe how research impacts public good).

1. **Procedures (includes intervention and description of which procedures are experimental/randomized):**

If you choose to participate, you will be asked to complete a survey/interview/behavioral games*.* This survey/interview/game will cover\_\_\_\_\_\_\_\_.

In this study, participants are ***randomly assigned*** to different versions/groups/treatments. While you be fully informed about the version/group/treatment of this study that you have been randomly assigned to, you will not be informed about different versions/groups/treatments of this study that other participants are in.

The survey will take approximately (duration) of your time. For participating in this survey, you will receive (compensation).

 We will return (number) times in the next (timeframe) for a follow-up survey/interview, but you are free to decline participation in the follow-up if you wish.

We hope to record a portion of this interview for (give reason for recording) purposes. This is voluntary, and you are free to decline if you do not wish to be recorded. (Include all relevant components for informing the participant about being recorded mentioned in the checklist)

We wish to record the GPS coordinates of this interview for (give reason) purposes. This does not pose any additional risk to you and is voluntary, so, you are free to decline if you feel uncomfortable.

1. **Risks and Rights:**

Participation is completely voluntary. [Insert whether there are any risks or outline questions that could distress participant. Choose option 1 or 2: (1) There are no anticipated risks from taking part in this interview. OR (2) You may experience distress over the nature of some questions]. You are free to decline participation, skip any question that makes you feel uncomfortable or stop the interview at any time. There is no penalty or loss of any existing benefits for doing so.

1. **Confidentiality:**

The answers you provide will be kept confidential to the extent possible (and allowable by law). The answers you provide will only be accessible to the research team and individuals from IPA who oversee the research. IPA will anonymize your personal data as soon as we no longer need it for IPA’s research. Data that cannot be linked to you personally may be used for research and academic publications. Only information that does not identify you may be shared with other people or organizations. You may be contacted to participate in a follow-up or another study at a future date.

1. **Contact Information (Further Questions) – Please list both:**

Project Associate/Coordinator name and ***local*** phone number, if they have questions about the research study.

A reviewing IRB / REC and their contact information, if they have questions about their rights as research participants

1. **Questions:**

Do you have any further questions?

**Response:**If I have answered all your questions, do you agree to participate in this study? (Surveyor should indicate subject’s response or have them sign their name.)

Yes\_\_\_\_ No\_\_\_\_

Do you agree to be contacted in the future for follow-up surveys?

Yes\_\_\_\_ No\_\_\_\_

Do you agree to be recorded?

Yes\_\_\_\_ No\_\_\_\_

Do you agree to have the GPS coordinates recorded?

Yes\_\_\_\_ No\_\_\_\_

1. Note: We **no longer** require projects to submit any documentation in local languages. [↑](#footnote-ref-1)
2. Pro-tip! See template at the end of this document for guidance on creating your informed consent! [↑](#footnote-ref-2)
3. These are required if they exist and apply to the study project; however, not every project has them. [↑](#footnote-ref-3)
4. A project is considered federally funded whenever funds come directly from a US Government Agency, funds come from a federal contractor, or funds come from another organization that is receiving funds from a US Government Agency. Please check your grant agreement to verify your own federal funding status. The rules and regulations for human subjects research are different for federally funded and non-federally funded studies. [↑](#footnote-ref-4)